

June 3, 2002

Mr. Ronald A. Milner, Chief Operating Officer
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT
REPORT NO. OAR-02-07, "OBSERVATION AUDIT OF THE OFFICE OF
CIVILIAN RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY
ASSURANCE, AUDIT NO. BSC-ARC-02-09"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report No. OAR-02-07. It is on the U.S. Department of Energy's (DOE's), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit of Bechtel SAIC Company, LLC (BSC), on May 6-10, 2002.

The OQA audit team (hereafter, audit team) performed a full-scope compliance-based quality assurance (QA) audit to evaluate BSC's implementation of the applicable provisions of the OCRWM Quality Assurance Requirements and Description document, DOE/RW-0333P, Revision 11, and associated implementing procedures relevant to BSC activities supporting the Yucca Mountain Site Characterization Project Office. During the audit, the audit team examined the effectiveness of the actions taken to correct deficiencies identified during the previous audits and surveillances performed by OQA.

The NRC observers (hereafter, observers) determined that DOE's audit of BSC was effective in identifying potential deficiencies and recommending improvements for the reviewed BSC activities. During the audit, both the audit team and the observers independently reviewed applicable QA procedures, and activities within the audit's scope.

Although the audit team identified potential deficiencies, and quality observations, the observers believe that BSC has shown improvement in the implementation of its QA program. The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit meeting.

R. A. Milner

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A written response to this letter and the enclosed report is not required; however, the open audit inquiry, LLNL-ARC-02-07, was discussed with the Bechtel/SAIC Procurement Quality Representative to explain the background and circumstances regarding the lack of documentation for receipt inspection performance. A response package has been prepared for management review and LLNL-ARC-02-07 remains open pending response.

The staff will continue to interface with OCRWM and follow the progress that BSC is making to address the issues identified during this audit. If you have any questions, please contact Ted Carter of my staff at (301) 415-6684.

Sincerely,
/RA/

Janet Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report
No. OAR-02-07, "Observation Audit of the
Office of Civilian Radioactive Waste Management,
Office of Quality Assurance, Audit No. BSC-ARC-02-09"

R. A. Milner

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Letter to R. Milner from J. Schlueter dated June 3, 2002

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C. Meyers, Moapa Paiute Indian Tribe

V. Miller, Fort Independence Indian Tribe

A. Bacock, Big Pine Paiute Tribe of
the Owens Valley

R. Quintero, Inter-Tribal Council of Nevada
(Chairman, Walker River Paiute Tribe)

M. Bengochia, Bishop Paiute Indian Tribe

J. Egan, Egan & Associates, PLLC

W. Briggs, Ross, Dixon & Bell

A. Funk, Mineral County, NV

E. Smith, Chemehuevi Indian Tribe

J. Charles, Ely Shoshone Tribe

D. Crawford, Inter-Tribal Council of Nevada

H. Blackeye, Jr., Duckwater Shoshone Tribe

D. Eddy, Jr. Colorado River Indian Tribes

J. Leeds, Las Vegas Indian Center

G. Runkle, DOE, Washington, DC

“OBSERVATION AUDIT OF THE
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT,
OFFICE OF QUALITY ASSURANCE,
AUDIT NO. BSC-ARC-O2-09”

1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management, and the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the U.S. Department of Energy's (DOE's) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA) audit of Bechtel SAIC Company (BSC), Las Vegas, NV.

The objectives of the OQA audit were to assess the adequacy and effectiveness of the Quality Assurance Requirements and Description (QARD) and implementing procedures, and to verify BSC's compliance with the requirements in the areas reviewed. The NRC observers' (hereafter, observers') objective was to assess the effectiveness of the OQA audit team (hereafter, audit team) and audit process, as well as the BSC implementation of the provisions in the QARD. This report documents the observers' determination of the effectiveness of the OQA audit, and the BSC implementation of QARD provisions.

2.0 MANAGEMENT SUMMARY

The observers determined that OQA Audit BSC-ARC-02-09 was effective in determining the level of compliance of BSC QA activities, with the QARD, and with associated implementing procedures. The observers agreed with the audit team's conclusions, findings, and recommendations. The observers found that the audit team members were qualified, independent of the activities that they reviewed, and knowledgeable of the QA requirements. Based on these observations, the OCRWM QA program had been satisfactorily implemented, except for the items noted in the six potential deficiencies reports (DRs), two Deficiency Identification and Referrals (DIRs), and eight Quality Observations (QOs). The potential DRs, DIRs, and QOs were in the areas of QA program requirements, nonconformances, software, and scientific investigation.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Ted Carter	Team Leader	NRC
Thomas C. Trbovich	QA Specialist	CNWRA
Mark R. Ehnstrom	QA Specialist	CNWRA

3.2 Audit Team

Donald Harris	Audit Team Leader	OQA/Navarro Quality Services (NQS)
Harvey Dove	Audit Team Leader In Training	OQA/NQS
Marilyn Kavchak	Auditor	OQA/NQS
Christian M. Palay	Auditor	OQA/NQS
Robert Toro	Auditor	OQA/NQS
James Voigt	Auditor	OQA/NQS

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

OQA conducted this audit of BSC in accordance with OCRWM QA Procedures AP 18.2Q, "Internal Audit Program," and AP 16.1Q, "Management of Conditions Adverse to Quality." The NRC staff's observation was based on NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

4.1 Audit Scope

The scope of the audit was to conduct a full-scope compliance-based audit to evaluate BSC's implementation of the OCRWM QA program defined in the QARD, DOE/RW-0333P, Revision 11, and applicable implementing procedures. The audit team evaluated the implementation, compliance, adequacy, and effectiveness of the QA program and procedures in place for activities supporting the Yucca Mountain Site Characterization Project (YMSCP). In addition, the audit evaluated the effectiveness of the actions completed to correct the deficiencies identified during the previous QA audits and surveillances.

4.2 Audit Conduct and Timing

The audit was performed in a professional manner and the audit team demonstrated a sound knowledge of the applicable BSC and DOE programs and procedures. The audit team personnel were unified in approach, persistent in their interviews, challenged responses when appropriate, and followed their checklist questions, deviating when necessary to more fully understand the BSC process or pursue discrepancies. The audit team performed a thorough and effective audit.

The audit team and observers caucused at the end of each day to discuss the audit status and any new and developing issues. The observers were encouraged to participate in the discussions with any comments, concerns, or questions. The audit team met with BSC management each morning, with some of the observers present, to discuss the current audit status and potential discrepancies. Members of the BSC organization also participated in the discussions via teleconference. The observers determined that the timing of the audit was appropriate for the team to evaluate the BSC QA program. It was also noted that the BSC personnel had a good understanding of the QA program requirements and accepted ownership of the products audited. The implementation of the QA program was improved over previous observation audits.

4.3 Audit Team Qualification and Independence

The observers determined that the qualifications of the audit team lead (ATL) and the OQA audit team members met the requirements of QAP-18.1, "Auditor Qualification." The ATL provided the qualification records for two auditors unknown to the observers. The observers concluded that the audit team members had the necessary expertise to perform the audit and had sufficient authority and organizational freedom to make the audit process meaningful and effective.

4.4 Examination of the QA Elements

The NRC staff observed the audit team conducting detailed checks of the adequacy of Bechtel/SAIC QA activities related to the YMSCP. The audit team effectively used its prepared checklist identifying the QA program implementing procedures. Interviews were held with Bechtel/SAIC personnel, as well as appropriate management personnel, who had performed or are currently performing activities required by the implementing procedures. Several record packages were also reviewed to assure documentation was in compliance with procedural

requirements. The audit team effectively shared information among team members and assisted one another to assure each area was adequately covered and completed.

4.4.1 Organization—LP-1.0Q-BSC, Revision 1 ICN 1

The audit team reviewed several organization charts of various Bechtel/SAIC groups. Administrative and functional reporting structures of the matrixed organizations (i.e., direct reporting of a staff member to an administrative and a technical manager) were not completely clear. These charts were discussed with the Bechtel/SAIC Projects Director, who agreed the charts could lead to confusion. Since the reorganization process is continuing, the audit team's recommendations will be incorporated into the revised organization charts.

The observers agreed with the findings in this area.

4.4.2 Software Management—AP-SI.1Q, Revision 3, ICN 3

The audit team reviewed three software packages, of which two were found to be in compliance with procedural requirements. However, the software, TCODMU, Version 1 (commonly referred to as Qconvert), which has been in continuous use for the Drift Scale Test data collection process at the site, was found to be in noncompliance. This software has been used for many years and apparently had not been qualified nor baselined. It was originally exempted from qualification, because it was classified as integral to measuring and test equipment. The audit team noted that the software contains 20 subroutines, none of which is associated with measuring and test equipment. The audit team also questioned why nobody had documented this known condition as a deficiency and in light of the management-imposed 'stand-down' on software usage, why nobody had obtained special authorization to continue use of this software. The audit team noted that a potential DIR would be made to the open Corrective Action Request, BSC-01-C-002, on this discrepancy.

The observers agreed with the audit team findings in this area and expressed concern at the closing meeting that with all the corrective actions taken and promised with regard to software qualification, unqualified software is still being found.

4.4.3 Procurement Document Control

The audit team reviewed documentation to assure compliance with three procurement procedures: LP-4.3Q-BSC, Revision 0 ICN 1, "Subcontracts"; LP-4.4Q-BSC, Revision 0 ICN 1, "Technical Service Agreements"; and LP-4.5Q-BSC, Revision 0 ICN 0, "Processing Purchase Requisitions." The audit team noted compliance with the documentation reviewed. However, it was noted that the procurement activities are aided by the use of a Procurement Directives Manual. This manual contains step-by-step instructions to complete various forms and guidance on meeting procedural requirements. This manual is not part of the quality system and is maintained by the Procurement Controller. Since personnel use this document to complete the various purchasing processes, the audit team recommended that the applicable administrative and line procedures should be referenced in the Manual, to better align it with the QA program.

The observers agreed with the audit team's findings in this area.

4.4.4 Scientific Notebooks—AP-SIII.1Q, Revision 1 ICN 1

The audit team reviewed three scientific notebooks for compliance with procedural requirements. The technical review of Scientific Notebook—Sandia National

Lab–SCI–024–Volume 1 had been properly accomplished. However, the Principal Investigator did not respond to, nor resolve, the technical reviewer's comments. The audit team identified a potential DR for this discrepancy.

In another scientific notebook, the audit team found that data were being entered on some occasions, two to three days after the work had been completed, rather than on the next work day, as required by procedure. The audit team identified a potential QO for this discrepancy.

The observers agreed with the audit team's findings in this area.

4.4.5 Technical Product and Data Review—AP–2–14Q, Revision 0 ICN 0

The audit team reviewed several data packages and determined that the required reviews were not being conducted in accordance with procedural requirements. Three occurrences were noted where the reviewer did not sign for concurrence on the Review Record. In other packages it was noted that mandatory comments were not resolved. There was no standard comment documentation, but comments were documented in three different ways; there was one occurrence where six out of eight Review Records had not been included in the records package. The audit team identified a potential DR for these conditions.

The observers agreed with the audit team's findings in this area.

4.4.6 Self-Assessments—AP–2.20Q, Revision 1 ICN 0

The audit team reviewed the Bechtel/SAIC/DOE/U.S. Geologic Survey schedule for self-assessments that had been updated on April 30, 2002. This schedule identified over 200 internal assessments that have been performed or will be performed during this fiscal year. Two completed assessment reports, one from the Purchasing, and one from the Projects, departments, were reviewed and found to be in compliance with the procedural requirements. The audit team noted that the reports were detailed and recommendations for improvements of the various processes were being documented in the Condition/Issue Identification and Reporting System. The audit team noted that the self-assessments were much better done than in previous audits.

The observers agreed with the audit team's findings in this area.

4.4.7 Potential Audit Findings

The audit team identified 16 conditions adverse to quality during its review. These conditions were identified as DRs, DIRs, and QOs. The following is a short description of each.

Six Potential DRs

- (1) Concurrence sections for technical reviewers were found to be incomplete on three Data Tracking Number packages.
- (2) There was no objective evidence showing that six of eight Review Records had been forwarded to the Review Coordinator or had been included in the record packages.
- (3) The Principal Investigator had not resolved the Technical Reviewer's comments that were in a Scientific Notebook.
- (4) No Record Road Maps were generated for three audited Data Tracking Number packages.

- (5) There was no objective evidence that indicated a technical review had been performed on two Data Tracking Number packages.
- (6) The Technical Data Management System does not contain any data for two Data Tracking Number packages that had been submitted in July and August 2001.

Two Potential DIRs

- (1) Software for the Drift Scale Test data is being used, which has not been qualified nor baselined.
- (2) Laboratory and key management personnel have received insufficient (incomplete) training as defined in the Science Training (CSO) Requirements Matrix, Revision 3.

Eight Potential QOs

- (1) The Quality Engineering Manager has not made the proper assignment of a Quality Engineering Representative to review a Technical Error Report. The authority to perform the assessment has not been delegated.
- (2) The person noted as having performed the Quality Assurance Representative Disposition Review on a Nonconformance Report was incorrect.
- (3) One Quality Assurance Representative had not granted signature authority to another Quality Assurance Representative regarding the close-out of a Supplier Discrepancies Report.
- (4) The Verification of Experience for an employee did not equal or exceed the minimum experience requirements of the job position description.
- (5) Scientific Notebook entries were not recorded by the next business day or work day, as required.
- (6) The Technical Data Management System database access list for the quarter following October 2001 was not submitted.
- (7) There was an incorrect quality review of the test plan.
- (8) There was a logging activity before the required distribution of the Authorization for Borehole Logging Activity form.

5.0 NRC STAFF FINDINGS

The observers determined that Audit No. BSC-ARC-02-09 was effective in determining the level of compliance of BSC activities in implementing the QA program.

The auditors reviewed selected project documents identified in the Audit Plan and employed a detailed checklist as the basis for their reviews. The audit team also examined related project documentation to verify the accuracy of source material and the status of data qualification activities. The auditors conducted interviews, with personnel with appropriate levels of knowledge, who were directly responsible for work packages reviewed. During the conduct of these interviews, the auditors effectively used the audit checklist to focus the inquiries on areas

of concern. The audit team also gave the observers adequate opportunities to provide comments, and to seek clarification on QA issues.

The observers agreed with the audit team's conclusion that BSC has shown improvement in implementing the provisions of the QARD, despite the identified deficiencies. The observers also expressed concern about the continuing identification of software-related deficiencies, despite the remedial and corrective actions, to prevent recurrence, related to inadequate software controls.

5.1 NRC AUDIT OBSERVER INQUIRIES

There were no audit observer inquiries initiated as a result of Audit BSC-ARC-02-09. However, the open audit inquiry, LLNL-ARC-02-07, was discussed with the Bechtel/SAIC Procurement Quality Representative, to explain the background and circumstances regarding the lack of documentation for receipt inspection performance. A response package has been prepared for management review.

The Audit Observer Inquiry, LLNL-ARC-02-07, remains open pending response.